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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/451,180	11/29/1999	WILFRIED FISCHER	29473/10458	8712

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EXAMINER	
GHALI, ISIS A D	
ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 07/01/2002 23

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/451,180	Applicant(s) FISCHER ET AL.	
	Examiner Isis Ghali	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 June 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,16-19 and 21-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 16-19, 21-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The receipt is acknowledged of applicants' amendment E, filed 06/04/2002.

Claims 1, 16-19, 21-29 are included in the prosecution.

Response to Arguments

1. Applicant's arguments with respect to claims 1, 16-19, 21-29 have been considered but are moot in view of the new ground(s) of rejection that necessitated by applicants' amendment E, in Paper No. 22:

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

2. Claims 1, 18-23, 25 and 29 are rejected under 35 U.S.C. 102(e) as being anticipated by US 5,965,155 ('155).

US '155 disclosed a multi-layered transdermal patch for the treatment of migraine, said patch comprising contact adhesive layer comprising clonidine in base comprising copolymer of 2-ethylhexyl acrylate and vinyl acetate and other acrylate polymers. The adhesive layer further comprises filler, a tackifier and a plasticizer (skin protective substance). The transdermal plaster comprising an impermeable backing and a protective layer, which is removed prior to use, such a layer is made of siliconized paper. The adhesive layer has weight per unit area of 125 g/m^2. See the abstract; col.1, lines 8-15, 54; col.3, lines12-43, 58-65; col.4, lines 5-9, 30-37, 65-67; col.5, lines 16-17.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1, 16-19, 21-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '155.

The teachings of US '155 are discussed under 102 rejection, however the reference does not teach the amount of clonidine and its delivery rate, and the materials for the backing.

It is within the skill in the art to select different materials for the backing and protective layers such as plastic, polyester, woven and non-woven fabric, and they all well known in the art. It is within the skill in the art to select optimal parameters such as ratios and weight percents of components as well as determining the dose of delivering a medication in order to achieve a beneficial effect. *See In re Boesch*, 205 USPQ 215 (CCPA 1980). Therefore, the weight percents of clonidine and its delivery rate instantly claimed are not considered critical absent evidence showing unexpected and superior results.

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to produce a transdermal device of US '155 that consists of backing layer; removable support layer; and pressure sensitive adhesive layer comprising clonidine, acrylate and 2-ethylhexyl acrylate and vinyl acetate copolymer, and determine the amount of the clonidine to obtain the desired delivery rate with reasonable expectation of success of the delivered device to provide the effective amount of clonidine to the patient in need. Motivation would arise logically from the transdermal art.

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 4,753,648 and US 4,358,494 both disclosed copolymer of 2-ethylhexyl acrylate and vinyl acetate. US 5,869,089 disclosed a transdermal therapeutic system to deliver clonidine.

Applicants traverse the rejection of claims 1, 16-19, 21-29 as being unpatentable over US '155 by arguing that:

- US '155 does not disclose a multi-layered transdermal patch for treatment of migraine.
- The patent is directed to a process of production for a transdermal patch and its application in prophylaxis and treatment of vasodilatation.
- The product comprises auxiliary agent and pentetrazole
- The reference does not teach remedy for the prophylactic treatment of all forms of migraine using clonidine.

In response to the above arguments, the examiner position is:

- US '155 disclosed a transdermal therapeutic system (TTS) comprising backing layer, active substance-containing self-adhesive reservoir layer, and removable protective layer, col.3, lines 25-30. Thus, the device is multilayered and is used to treat migraine, col.1, lines 15, 47.
- The reference clearly teaches in its abstract that the invention relates to a product and the process of its production. The reference also teaches that the

migraine are caused by the vasodilatation of the blood vessels, and accordingly, treatment of vasodilated blood vessels will necessary treat migraine when it is present as a symptom of the vasodilatation.

- The expression "comprising " permits the presence of other ingredients such as other drugs and auxiliary agents, and does not preclude the presence of other ingredients, active or inactive, even in major amounts. See *Moleculon Research Corporation v CBS, Inc.* 229 USPQ 805, *In re Baxter* 210 USPQ 795, 803. In any events, applicants' claim 18 adds auxiliary agents such as filler, skin-protective substances and tackifiers.
- The reference disclosed treatment of migraine using clonidine, col.1, lines 47-55. Applicants are not claiming any particular form of migraine.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (703) 305-4048. The examiner can normally be reached on Monday through Thursday from 7:00 AM to 5:30 PM, Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Isis Ghali
Examiner
Art Unit 1615

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600